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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,753	03/29/2004	Donald K. Jones	CRD5067	2837
27777	7590	02/13/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			LANG, AMY T	
			ART UNIT	PAPER NUMBER
			3731	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/13/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/811,753	JONES ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Amy T. Lang	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 March 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-40 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-40 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/30/2006, 4/29/2005</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Specification***

1. The disclosure is objected to because of the following informalities: page 3, line 20 includes the phrase "the coil in order to expose," where the word "to" is missing.

Appropriate correction is required.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **Claims 1-4, 6-26, and 28-40** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 11 of copending Application No. 11/171,560 (US 2006/0058834 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of US '834 discloses an embolic occlusion device comprising a coil. Claims 7 and 11 further disclose wherein the coil is coated with an elastomeric coating of glycolide and  $\epsilon$ -caprolactone copolymers.

Applicants' attention is drawn to MPEP 804 where it is disclosed that "the specification can always be used as a dictionary to learn the meaning of a term in a patent claim." *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in an application defines an obvious variation of an invention claimed in the patent. (underlining added by examiner for emphasis) *In re Vogel*, 422 F.2d 438, 164 USPQ 619,622 (CCPA 1970).

Consistent with the above underlined portion of the MPEP citation, attention is drawn to where US '834 discloses this mixture as comprising from about 35 to 45 wt% of  $\epsilon$ -caprolactone, with the rest being glycolide ([0021]). Furthermore, the percent elongation of the mixture is greater than 200 or greater than 500 ([0020]). The embolic coil is defined as comprising a metallic material ([0028]).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Slaikeu (US 6,231,590 B1) in view of Bezwada (US 5,713,920).

Slaikeu discloses an embolic occlusion device comprising a helically wound metallic coil (column 3, lines 6-23). The coil is coated with a biodegradable polymer, specifically a copolymer of glycolide and  $\epsilon$ -caprolactone (column 6, lines 5-15). However, Slaikeu is silent regarding the wt% of each compound.

Bezwada also discloses a coating composition comprising a copolymer of glycolide and  $\epsilon$ -caprolactone (column 2, lines 57-64; column 4, lines 47-48). Specifically, Bezwada teaches the coating mixture comprising from about 35 to 45 wt% of  $\epsilon$ -caprolactone with the rest being glycolide (column 4, line 54 through column 5, line 2). This produces an elastomeric bioabsorbable coating that is advantageous for

medical devices (column 3, lines 1-8). The percent elongation of the mixture is further defined as greater than about 200, preferably greater than about 500 (column 3, lines 35-38). The copolymer is also disclosed with a percent crystallinity, as measured by x-ray diffraction, less than about 25% (column 4, lines 35-40).

Bezwada teaches that the disclosed elastomeric coating copolymer of glycolide and  $\epsilon$ -caprolactone is used for many medical devices (column 6, lines 14-332). Slaikeu discloses a medical device coated with a copolymer of glycolide and  $\epsilon$ -caprolactone but is silent regarding the wt% of each component. Therefore, since Bezwada teaches the same mixture wherein the amount of each component is specifically added to produce an advantageous mixture, it would have been obvious to one of ordinary skill in art at the time of the invention for Slaikeu to also use the wt% of  $\epsilon$ -caprolactone and glycolide as disclosed by Bezwada.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

02/07/2007

ANH  
ANH TUANT.NGUYEN

  
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**SUPERVISORY PATENT EXAMINER**

2/9/07